DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 20 1999

NADA 141-120

Janice B. Reid
Regulatory Affairs Support Supervisor
Novartis Animal Health
Pinecroft Road, Suite 400
Greensboro, NC 27407

Dear Dr. Reid:

We refer to your Drug Experience Reports dated January 6 and 8, 1999. In the January 6 Information Kit submission, ten promotional pieces were received consisting of: Information Box, Video, Client Brochure, Countertop Display, Fold-Out Brochure, Consultation Form, Q&A Sheet, Technical Review, and Materials Sheet. In the January 8 News Release submission, two promotional pieces were received consisting of: Video and Cassette. First, The Client Brochure coded "CLM 980005A" has a false and misleading statement on the front "*End the suffering of separation anxiety.*" Clomicalm may relieve or reduce the signs of separation anxiety but it does not eliminate separation anxiety. Clomicalm indications are: "to be used as part of a comprehensive behavior management program to treat separation anxiety in dogs greater than 6 months of age. Inappropriate barking or destructive behavior, as well as inappropriate elimination (urination or defecation) may be alleviated by the use of Clomicalm Tablets in conjunction with behavior modification." Therefore, Clomicalm is indicated only for the alleviation of separation anxiety and not a cure as implied on the front of the Client Brochure. Second, the Client Brochure does not give fair balance in the body of the brochure. The safety and efficacy of Clomicalm are described but side effects are not mentioned. Third, a brief summary appears on the last page of the brochure. This brochure is considered labeling under 21 CFR 202.1(l)(2), as such should include full disclosure information; in other words, a reproduction of the package insert rather than brief summary. This also applies to the Client Insert on page 25 of the Clinical and Technical Review in the Information Box for veterinarians.

Although a Readers Digest advertisement was not included in the Drug Experience Reports (dated January 6 and 8, 1999), this ad has come to our attention which fails to provide fair balance in the body of the ad. Again, side effects are not mentioned in the ad. 21 CFR 202.1(e)(3)(i) states that "The requirement of a true statement of information relating to side effects, contraindications, and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in any other distinct part of the advertisement of a brief

statement containing true information relating to side effects, contraindications, and effectiveness of the drug". This ad was discussed with Dr. Sharon Redman on March 17, 1999, in a telephone conversation.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356V, that you will promote your product only in accordance with the labeling provided for in the approved application. We ask that you immediately discontinue any further dissemination of these objectionable advertising pieces and provide fair balance in all of your future promotional materials.

Please inform us of your intentions as soon as possible, or in any event within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely,

Mohammad I. Sharar, DVM, MSc.
Team Leader, Marketed Product Scientific
And Review Team II , HFV-216
Division of Epidemiology and Surveillance
Office of Surveillance and Compliance